

features. Event rates were estimated with the Kaplan-Meier method and compared with a log-rank test. Cox regression analysis was performed to determine the difference in hazard ratios for all cause mortality at one year and adjusted for variables that could not be included in the propensity score, such as TIMI 3 flow post procedure and the use of GP IIb/IIIa inhibitors.

Results: One year follow-up was complete in 3131 patients (99.6%). In total, 284 patients died within 1 year (9.0%). In the thrombus aspiration group, 120 patients died (7.6%), whereas 164 died in the control group (10.4%, $p = 0.006$). Thrombus aspiration was associated with a hazard ratio of 0.72 (95% CI 0.57 - 0.91, $p = 0.006$). After correction for statistically significant different distributed variables, Cox regression yielded a hazard ratio of 0.69 (95% CI 0.52 - 0.91, $p = 0.009$) for 1 year all cause mortality.

Conclusion: The routine use of thrombus aspiration was associated with reduced one year mortality in this large real-world patient cohort. These data strongly support the observed survival benefit in the TAPAS trial.

TCT-83

Two-Year Clinical Follow-up Comparing Eptifibatide and Abciximab in Patients Undergoing Primary Percutaneous Revascularization for ST-Elevation Myocardial Infarction Results from the HORIZONS-AMI Trial

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Background: The GPIIb/IIIa inhibitors (GPI) eptifibatide and abciximab are both commonly used in patients with acute ST-segment elevation myocardial infarction (STEMI) undergoing percutaneous coronary intervention (PCI). However, comparative effectiveness data are lacking.

Methods: In this sub-study of the HORIZONS-AMI trial, we compare the 2-year clinical outcomes of patients of the heparin plus GPI (control) group treated with abciximab ($n = 907$) versus eptifibatide ($n = 803$) prior to primary PCI. The GPI assignment was not randomized, but defined pre-randomization. Rates of both major bleeding and net adverse clinical events (NACE - consisting of death, reinfarction, target vessel revascularization for ischemia, stroke, and major bleeding) are reported.

Results: The 2 groups were similar in regards to patient comorbidities, conjunctive anti-thrombotic therapies, lesion severity, and initial PCI strategy. At 30 days, both eptifibatide and abciximab resulted in similar NACE (12.8% vs. 12.7%, hazard ratio [95% confidence interval] = 0.99 [0.76, 1.30], $P = 0.97$) or in bleeding rates (11.4% vs. 9.9%, hazard ratio [95% confidence interval] = 1.05 [0.77, 1.44], $P = 0.74$) between both GPI. At 2-year follow-up, eptifibatide and abciximab maintained equivalent outcomes of NACE (24.5% vs. 25.5%, hazard ratio [95% confidence interval] = 0.96 [0.79, 1.17], $P = 0.69$) and similar rates of major bleeding (10.7% vs. 11.9%, hazard ratio [95% confidence interval] = 0.90 [0.67, 1.19], $P = 0.44$). Ischemic and bleeding complications are summarized in Table 1 below.

Conclusion: In patients with STEMI undergoing primary PCI in the HORIZONS-AMI trial, GPI treatment with abciximab and eptifibatide demonstrated similar bleeding risks and clinical efficacy after 2-year follow-up.

TCT-84

Hypothermia in Acute MI: Rationale and Results of the RAPID MI-ICE Study

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Background: Hypothermia as adjunct treatment to reperfusion in acute coronary occlusions has in animal models been shown to reduce infarct size if induced prior to reperfusion, but appears to have no effect if induced after the reperfusion takes place. The use of adjunct hypothermia treatment was then tested in the COOL-MI and ICE-IT studies in patients with ST elevation acute myocardial infarction (STEMI) scheduled for PCI. However, both trials failed. It is likely that the slow cooling process to $<35^{\circ}\text{C}$ coupled with a faster door to balloon time resulted in only a minority of patients reaching target temperature prior to reperfusion. Following animal research, we aimed to evaluate the safety and feasibility of rapidly induced hypothermia before reperfusion in patients with STEMI.

Methods: 20 patients with STEMI scheduled for primary PCI were enrolled in this prospective randomized study. Hypothermia was rapidly induced by a combination of rapidly infused cold saline solution and endovascular cooling catheters. After 4-2 days, myocardium at risk (MaR) and infarct size (IS) were assessed by cardiac magnetic resonance using T2-weighted imaging and late gadolinium enhancement imaging, respectively.

Results: The target temperature of $<35^{\circ}\text{C}$ ($34.7 \pm 0.3^{\circ}\text{C}$) was achieved before reperfusion without significant delay in door-to-balloon time (43 ± 7 min vs. 40 ± 6 min, hypothermia vs. controls, $p = 0.12$). Despite similar duration of ischemia (174 ± 51 min vs. 174 ± 62 min, hypothermia vs. controls, $p = 1.00$), IS normalized to MaR was reduced by 38% in the hypothermia group compared to the controls ($29.8 \pm 12.6\%$ vs. $48.0 \pm 21.6\%$, $p = 0.04$).

Conclusion: The protocol demonstrates the ability and safety of reaching the target temperature of $<35^{\circ}\text{C}$ before reperfusion without delaying primary PCI, and this combination hypothermia as an adjunct therapy in STEMI resulted in a 38% reduction in infarct size.

TCT-85

Why Does Primary Angioplasty Not Work In Observational Studies When It Works Consistently In Randomised Controlled Trials? An Analysis Of 54,360 Patients With ST Elevation Myocardial Infarction

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Introduction: A recent meta-analysis of registries suggests that primary angioplasty (PPCI) and fibrinolysis give equivalent long term survival in 'real-world' practice'. But meta-analyses of randomised controlled trials (RCTs) have consistently demonstrated better survival with PPCI. These conflicting results lead to the controversial possibility that primary angioplasty may not be beneficial in the 'real world'. One explanation for this paradox could be that, in the 'real world', patients with a high risk of mortality are being preferentially allocated to angioplasty. If true, it is important to demonstrate to prevent cardiologists making incorrect conclusions from registry results.

Methods: We analysed the published registries (54,360 patients) for allocation of high-risk patients (cardiogenic shock or equivalent) to determine if the choice of reperfusion therapy was affected by the risk level of the patient. A weighted least squares regression was used to determine the relationship between high risk patient distribution and registry outcomes.

Results: In 10 of the 11 registries, there were data on cardiogenic shock or its equivalent. In 7

registries high-risk patients were preferentially allocated to PPCI (8.4% high risk in PPCI versus 3.1% fibrinolysis, $p < 0.0001$). In the others, the converse was true (3.9% versus 12.2%, $p < 0.0001$). The therapy receiving excess high risk patients had worse outcomes ($r = -0.84$, $p < 0.003$). After accounting for this selection bias, PPCI gave 34% lower mortality than fibrinolysis (OR 0.66, 95% CI 0.55-0.80, $p = 0.001$).

Conclusion: The conflicting results of RCTs and registries in this field can be explained by selection bias of high risk patients. When we account for this, registry data actually concur with RCT data and PPCI is confirmed as the treatment of choice for STEMI in the 'real world'.

'Huynh T, Perron S, O'Loughlin J, Joseph L, Labrecque, Tu, Theroux. Circulation 2009; 119(24):3101-9.

TCT-86

Health Care System Delay Predicts Mortality In ST-Elevation Myocardial Infarction Patients Treated With Primary Percutaneous Coronary Intervention

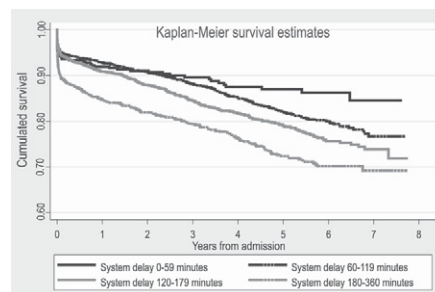
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Context: Timely reperfusion therapy is recommended for patients with ST-elevation myocardial infarction (STEMI), and door-to-balloon (D2B) delay has been proposed as a performance measure in triaging patients for primary percutaneous coronary intervention (PPCI). However, focusing on the time from first contact with the health care system to the initiation of reperfusion therapy (system delay) may be more relevant, because it constitute the total time to reperfusion modifiable by the health care system. No previous studies have focused on the association between system delay and outcome in patients with STEMI treated with PPCI.

Objective: To evaluate the associations between system, treatment, patient, and D2B delays and mortality in patients with STEMI.

Design, Setting, and Patients: The study was based on population-based Danish medical registries of patients with STEMI that were treated with PPCI from January 1, 2002 to December 31, 2008 in Western Denmark. Crude and adjusted hazard ratios (HR) of mortality were obtained by Cox proportional regression analysis. Patients ($n = 7642$) underwent PPCI within 12 h of symptom onset. The median follow-up time was 3.4 years.

Results: System delays of <1 h, 1-2 h, 2-3 h, and 3-6 h corresponded to long-term cumulative mortality rates of 15.4%, 23.3%, 28.1%, and 30.8% ($P < 0.001$). In multivariable analysis adjusted for other predictors of mortality, system delay was independently associated with mortality (adjusted HR = 1.10 per hour delay, 95% confidence interval 1.04-1.16), as was its components: prehospital system delay and D2B delay.



Conclusion: Health care system delay is associated with mortality in STEMI patients treated with PPCI. In triaging patients, focus on system delay as a performance measure may be of value to achieve optimal triage both in the prehospital phase and at the hospital.

TCT-87

STEMI Presentation During Off-Hours Does Not Compromise Response Times or Mortality: A HORIZONS-AMI Substudy

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Background: Retrospective registries have indicated higher short-term mortality in patients admitted with ST-elevation myocardial infarction (STEMI) during Off-hours; this may be due to differences in door-to-balloon time between On versus Off-hours.

Methods: STEMI patients prospectively enrolled and followed in the randomized multicenter HORIZONS-AMI study were categorized by their admission arrival time into On-Hours (work days Monday through Friday from 8am to 5pm) versus Off-Hours. In this analysis, we selected the subset of patients who presented directly to hospitals with 24/7 primary PCI availability. We assessed both major bleeding and MACE (death, reinfarction, TVR, stroke), as well as their combined net adverse cardiovascular event rate (NACE) up to 2 years.

Results: 2440 patients with STEMI were enrolled within 12 hours of symptom onset at 123 hospitals in 11 countries. Of these 586 (24%) presented during On-Hours and 1854 (76%) during Off-Hours. Baseline demographic characteristics were similar between both groups. Vascular closure devices were used more commonly during Off-hours (25.8% vs 30.9% vs. $p = 0.027$). Table 1 summarizes treatment strategy, MACE and bleeding complications. Net adverse event rates were similar between